

**UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF NORTH CAROLINA  
CHARLOTTE DIVISION  
CIVIL ACTION NO. 3:06CV368-C**

**HEATHER MICHELLE** )  
**HORNE, Administratrix of the** )  
**Estate of Zachary Clifton Horne,** )  
**Deceased,** )  
 )  
**Plaintiff,** )  
**v.** )  
 )  
**NOVARTIS** )  
**PHARMACEUTICALS** )  
**CORPORATION,** )  
 )  
**Defendant.** )  
\_\_\_\_\_ )

**MEMORANDUM AND RECOMMENDATION**

**THIS MATTER** is before the Court on the “Defendant Novartis Pharmaceuticals Corporation’s Motion to Dismiss” (document #10) and “. . . Memorandum in Support . . .” (document #11), both filed October 6, 2006. On November 17, 2006, the Plaintiff filed her “. . . Response to Motion to Dismiss” (document #24). The Defendant filed its “. . . Reply to Response to Motion to Dismiss” (document #25) on December 13, 2006.

This matter was referred to the undersigned Magistrate Judge pursuant to 28 U.S.C. § 636(b)(1)(B), and the Defendant’s Motion is now ripe for the Court’s consideration.

Having fully considered the arguments, the record, and the applicable authority, the undersigned will respectfully recommend that the Defendant’s Motion to Dismiss be granted, as discussed below.

**I. PROCEDURAL AND FACTUAL BACKGROUND**

This is an action seeking damages for the death of Zachary Clifton Horne based on the

Defendant's alleged negligence, wantonness, failure to warn, breach of warranty of merchantability, fraud, misrepresentation, and suppression of allegedly adverse information regarding the safety of Lotensin HCT® ("Lotensin").

Accepting the allegations of the Complaint as true, the Defendant is the manufacturer of Lotensin, an angiotensin-converting-enzyme ("ACE") inhibitor type of blood pressure medication. The Plaintiff had been taking Lotensin for several years prior to becoming pregnant with her first child in October 2003. The Plaintiff was seven weeks and four days pregnant when her doctor advised her to stop taking Lotensin, a recommendation she followed. She then delivered her son, Zachary Clifton Horne, July 9, 2004 – at a gestational age of thirty-six weeks and four days. Zachary lived for only nineteen days, dying as a result of defects in his heart and kidney on July 28, 2004.

The Plaintiff alleges that the Defendant promoted Lotensin as safe for use during the first trimester of pregnancy in spite of "knowledge of reported incidents of birth defects associated with first trimester use of ACE Inhibitor blood pressure medicines such as Lotensin HCT®, and studies revealing birth defects to infants after first trimester use of ACE Inhibitors by the mothers." Specifically, the Lotensin August 2003 package insert<sup>1</sup> contains the following warnings:

---

<sup>1</sup>Although the Plaintiff did not attach the actual package insert to her Complaint, she explicitly refers to the warnings. Thus, the warning may be considered in this Motion to Dismiss. See American Chiropractic Assoc., Inc. v. Trigon Healthcare, Inc., 367 F.3d 212, 234 (4th Cir. 2004) (stating that "when a defendant attaches a document to its motion to dismiss, a court may consider it in determining whether to dismiss the complaint [if] it was integral to and explicitly relied on in the complaint and [if] the plaintiffs do not challenge its authenticity") (internal citations and quotations omitted).

#### **USE IN PREGNANCY**

**When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus.** When pregnancy is detected, Lotensin HCT should be discontinued as soon as possible. See **WARNINGS, Fetal/Neonatal Morbidity and Mortality.**

\* \* \*

#### **Fetal/Neonatal Morbidity and Mortality**

ACE inhibitors can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature. When pregnancy is detected, Lotensin HCT should be discontinued as soon as possible.

The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE-inhibitor exposure.

These adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to ACE inhibitors only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should make every effort to discontinue the use of benazepril as soon as possible.

Rarely (probably less often than once in every thousand pregnancies), no alternative to ACE inhibitors will be found. In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intraamniotic environment.

\* \* \*

No teratogenic effects were seen when benazepril and hydrochlorothiazide were administered to pregnant rats at a dose ratio of 4:5. On a mg/kg basis, the doses used were up to 167 times the maximum recommended human dose. Similarly, no

teratogenic effects were seen when benazepril and hydrochlorothiazide were administered to pregnant mice at total doses up to 160 mg/kg/day, with benazepril:hydrochlorothiazide ratios of 15:1. When hydrochlorothiazide were administered to pregnant mice and rats during their respective periods of major organogenesis at doses up to 3000 and 1000 mg/kg/day respectively, there was no evidence of harm to the fetus. Similarly, no teratogenic effects of benazepril were seen in studies of pregnant rats, mice, and rabbits; on a mg/kg basis, the doses used in these studies were 300 times (in rats), 90 times (in mice), and more than 3 times (in rabbits) the maximum recommended human dose.

Defendant's Memorandum in Support (Exhibit A).

The Plaintiff argues that while this package insert does warn against the use of Lotensin during the second and third trimesters of pregnancy, it improperly "proactively state[s] that fetal injury does not appear to be associated with use of Lotensin HCT® during the first trimester of pregnancy." The Plaintiff provides support for this allegation by citing a June 7, 2006 Public Health Advisory from the Food and Drug Administration ("FDA") which warned that the use of ACE inhibitors during the first trimester of pregnancy may increase the risk of serious birth defects, although the FDA did not plan to change the pregnancy categories (which categorize drugs based on their potential hazards to the unborn baby) based on one observational study. The Plaintiff also notes a June 8, 2006 New England Journal of Medicine article publishing the results of a study "in which investigators found that infants exposed to ACE Inhibitors during their first trimester of gestation were found to be at a significant increased risk of birth defects."<sup>2</sup>

The Plaintiff filed her Complaint in the Superior Court Division of Mecklenburg County on July 27, 2006. On August 28, 2006, the Defendant removed the action to this Court. Removal has not been challenged and appears proper. The Defendant filed its Answer and the subject Motion on

---

<sup>2</sup>The undersigned notes that each of these events occurred over two years after the Plaintiff stopped taking Lotensin.

October 6, 2006, arguing that all of the Plaintiff's claims have been preempted by federal law and the FDA's regulations. As noted above, the Motion to Dismiss has been fully briefed and is, therefore, ripe for determination.

## **II. DISCUSSION OF CLAIMS**

### **A. Standard of Review**

"A motion to dismiss under [Fed. R. Civ. P. 12(b)(6)] tests the sufficiency of a complaint; importantly, it does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." Republican Party of North Carolina v. Martin, 980 F.2d 943, 952 (4th Cir.), cert. denied, 510 U.S. 828 (1993), citing 5A C. Wright & A. Miller, Fed. Practice and Procedure §1356 (1990).

"A motion to dismiss for failure to state a claim should not be granted unless it appears to a certainty that the plaintiff would be entitled to no relief under any state of facts which could be proved in support of [the subject] claim." McNair v. Lend Lease Trucks, Inc., 95 F.3d 325, 328 (4th Cir. 1996) (en banc), citing Rogers v. Jefferson-Pilot Life Ins. Co., 883 F.2d 324, 325 (4th Cir. 1989); and Johnson v. Mueller, 415 F.2d 354, 355 (4th Cir. 1969). Accord Republican Party of NC, 980 F.2d at 952 ("A complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief") (internal citation omitted).

In considering a Rule 12(b)(6) motion, the complaint must be construed in the light most favorable to the nonmoving party, assuming factual allegations to be true. See, e.g., Hishon v. King & Spalding, 467 U.S. 69, 73 (1984); Scheuer v. Rhodes, 416 U.S. 232, 236 (1974); Mylan Labs., Inc.

v. Matkari, 7 F.3d 1130, 1134 (4th Cir. 1993); Martin Marietta v. Int'l Tel. Satellite, 991 F.2d 94, 97 (4th Cir. 1992); and Revene v. Charles County Comm'rs, 882 F.2d 870, 872 (4th Cir. 1989).

### **B. Preemption of the Plaintiff's State Law Claims**

The Food, Drug, and Cosmetic Act, 21 U.S.C. § 355, gives the FDA control over the regulation of the prescription drug industry – vesting “the FDA with authority to regulate the specifics of drug labeling, making important judgments of what is required for safety of the consuming public, what new drugs may appear in the marketplace, and what warnings their instructions and labels must carry.” Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 518 (E.D. Pa. 2006). In approving a new drug, the FDA requires extensive information from the manufacturer, including, among other things, the proposed text of the labeling, pharmacologic and toxicologic studies, clinical investigation data, case report forms, and patent information. See 21 C.F.R. § 314.50. Further, after the extensive approval process, the manufacturer must continue to provide the FDA with updated information concerning the drug's labeling, marketing information, clinical trials, adverse drug experiences, etc. See 21 C.F.R. § 314.80-81. However, a manufacturer may distribute an approved drug with an added or strengthened “contraindication, warning, precaution, or adverse reaction” label “upon receipt by the [FDA] of a supplement for the change.” 21 C.F.R. § 314.70(c)(6)(iii)(A).

Given the extensive federal regulation in this area of the law, the essential issue becomes whether the extensive federal role in governing the safety of prescription drugs preempts the Plaintiff's state law claims.

Pursuant to the Supremacy Clause of the United States Constitution, any state law which

materially conflicts with the exercise of an enumerated federal power is preempted. There are three ways in which federal preemption occurs: (1) where Congress expressly preempts state law; (2) where preemption is implied because Congress has occupied the entire field; or (3) where preemption is implied because there is an actual conflict between state and federal law. See, e.g., Schneidewind v. ANR Pipeline Co., 485 U.S. 293, 299-300 (1988). The Defendant argues that the Plaintiff's claims fall in this third category, evoking implied conflict preemption where "it is impossible for a private party to comply with both state and federal requirements, . . . or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Geier v. American Honda Motor Co., Inc., 529 U.S. 861, 899 (2000) (citations and quotations omitted).

Because the Supreme Court has consistently recognized that "considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer," Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984) (citations omitted), the FDA's position on preemption must be given deference. And indeed, the FDA has concluded that state law claims concerning the labeling of prescription drugs are preempted by federal law.<sup>3</sup> See 71 Fed. Reg. 3922, 3934-36 (Jan. 26, 2006) ("Preemption Preamble"). The

---

<sup>3</sup>The FDA has made the following statement concerning preemption in its Preemption Preamble:

Consistent with its court submissions and existing preemption principles, FDA believes that at least the following claims would be preempted by its regulation of prescription drug labeling:

(1) Claims that a drug sponsor breached an obligation to warn by failing to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling;

(2) claims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling, in those cases where a drug's sponsor has used Highlights consistently with FDA draft guidance regarding the "brief summary" in direct-to-consumer advertising . . . ;

Preemption Preamble identifies the FDA's concern over competing state laws as follows:

If State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation of drugs would be disrupted.

71 Fed. Reg. at 3969.

In addition to the FDA's unequivocal statement on this issue, other courts have examined the question of preemption in this field and concluded that state law claims based on the premise of a failure to warn in regards to prescription drugs are preempted. See, e.g., Colacicco, 432 F. Supp. 2d at 536-38 (noting that "Congress established the elaborate system of legislation for the introduction of new drugs" and that state law claims were not envisioned by Congress); and Ehlis v. Shire Richwood, Inc., 233 F. Supp. 2d 1189, 1198 (D.N.D. 2002) (finding that the "FDA dictates the contents of the label . . . and defendants were prohibited from changing it without prior approval

---

(3) claims that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule, including § 201.57(c)(5) (requiring that contraindications reflect "[k]nown hazards and not theoretical possibilities") and (c)(7);

(4) claims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had the obligation to warn);

(5) claims that a drug sponsor breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising; and

(6) claims that a drug's sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug's label (unless FDA has made a finding that the sponsor withheld material information relating to the statement).

71 Fed. Reg. at 3935-36.

from the FDA, except in limited circumstances for a limited period of time”).<sup>4</sup> As the district court persuasively put it in Colacicco, “it is far more desirable that the important issues presented by this case, indeed tragic in its facts, are better addressed by elected officials, legislative and executive, than by . . . judges, a belief which itself has been echoed by the Supreme Court.” 432 F. Supp. 2d at 536 (citations omitted).

Applying these foundational principles to the Plaintiff’s state claims, it is clear that each is preempted and therefore must be dismissed. The underlying basis for each claim is that the Defendant failed to properly label and warn the Plaintiff of the potential for harm. The Court agrees with the published and unpublished authority concluding that Congress intended for the FDA – not state or individual federal courts – to decide what a prescription drug label must contain. Further, the Court must give considerable weight to the FDA’s determination that state law claims, such as those presented here, which would impose different or additional duties on a drug manufacturer disrupt the federal system for regulation of drugs. In other words, if these state law claims were allowed to proceed, they would clearly conflict with plainly stated purposes and objectives of Congress.

Accordingly, the undersigned will respectfully recommend that Motion to Dismiss be granted.

---

<sup>4</sup>Recognizing that unpublished authority is of limited precedential value, the undersigned nonetheless notes that several other courts have also agreed with this proposition. See Abramowitz v. Cephalon, Inc., 2006 WL 560639, \*4 (N.J. Super. L. Mar. 3, 2006) (giving weight to the Preemption Preamble and finding that “the FDA clearly intends for FDA approval of labels . . . to preempt state claims”); Needleman v. Pfizer, Inc., 2004 WL 1773697, \*2 (N.D. Tex. Aug. 6, 2004) (refusing to consider evidence which conflicted with the FDA’s requirements for drug manufacturer’s label); and Dusek v. Pfizer, Inc., 2004 WL 2191804, \*8 (S.D. Tex. Feb. 20, 2004) (finding that if the plaintiff’s failure to warn claim were allowed to proceed, the defendant could be held liable for “not including a warning that the FDA explicitly decided was not scientifically warranted, a decision the FDA reconfirmed *after* the date of decedent’s death”) (emphasis in original).

### **III. RECOMMENDATION**

**FOR THE FOREGOING REASONS**, the undersigned respectfully recommends that the Defendants' Motion to Dismiss (document #10) be **GRANTED**.

### **IV. NOTICE OF APPEAL RIGHTS**

The parties are hereby advised that, pursuant to 28 U.S.C. §636(b)(1)(c), written objections to the proposed findings of fact and conclusions of law and the recommendation contained in this Memorandum must be filed within ten (10) days after service of same. Page v. Lee, 337 F.3d 411, 416 n.3 (4th Cir. 2003); Snyder v. Ridenour, 889 F.2d 1363, 1365 (4th Cir. 1989); United States v. Rice, 741 F. Supp. 101, 102 (W.D.N.C. 1990). Failure to file objections to this Memorandum with the district court constitutes a waiver of the right to de novo review by the district court. Diamond v. Colonial Life, 416 F.3d 310, 315-16 (4th Cir. 2005); Wells v. Shriners Hosp., 109 F.3d 198, 201 (4th Cir. 1997); Snyder, 889 F.2d at 1365. Moreover, failure to file timely objections will also preclude the parties from raising such objections on appeal. Diamond, 416 F.3d at 316; Wells, 109 F.3d at 201; Page, 337 F.3d at 416 n.3; Thomas v. Arn, 474 U.S. 140, 147 (1985); Wright v. Collins, 766 F.2d 841, 845-46 (4th Cir. 1985); United States v. Schronce, 727 F.2d 91 (4th Cir. 1984).

The Clerk is directed to send copies of this Memorandum and Recommendation to counsel for the parties; and to the Honorable Robert J. Conrad, Jr.

**SO RECOMMENDED AND ORDERED.**

Signed: January 8, 2007

*Carl Horn, III*

---

Carl Horn, III  
United States Magistrate Judge

